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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
(SAN FRANCISCO DIVISION)

In re: **VIAGRA (SILDENAFIL CITRATE) PRODUCTS LIABILITY LITIGATION** This Document Relates to: ALL ACTIONS	**Master File No.: 3:16-md-02691-RS** **PLAINTIFFS' POSITION STATEMENT PURSUANT TO PRETRIAL ORDER # 1**

Proposed Lead Counsel Ernest Cory of Cory Watson, P.C., with the support of Plaintiffs' Leadership Structure, respectfully submits this Position Statement on behalf of Plaintiffs in this MDL and pursuant to Pretrial Order No. 1.[1]

INTRODUCTION

Pfizer has created a public health emergency. Pfizer knew or should have known years ago that Viagra (sildenafil citrate), which is used to treat erectile dysfunction ("ED"), could

[1] The undersigned thank the law firm of Robins Kaplan LLP for taking primary responsibility for researching and drafting significant portions of this Position Statement. The undersigned has extensive Mass Tort, complex litigation, and MDL experience, has been actively involved in the development of this litigation, and has applied for Plaintiffs' Lead Counsel in this MDL. Prior to filing, this Statement was circulated to all known counsel of record for Plaintiffs in this MDL.

cause melanoma. Approximately 30 million men in the United States alone are affected by ED.[2] More than 23 million men have been prescribed Viagra.[3] Introduced to the U.S. market in 1998, Viagra holds approximately 45% of the U.S. market share for ED medications.[4] In 2012 alone, physicians reportedly wrote eight million prescriptions for Viagra.[5] Despite its widespread use, it is not a life-saving medication. The scientific studies that associate its use with the development of cancer—particularly melanoma, the deadliest form of skin cancer[6]—raise real questions about the drug's risks and benefits.

This is a failure to warn case. Pfizer should have known, or worse knew and ignored, that Viagra could impact melanoma development and should have warned users and the medical community of this risk. As an inhibitor of the cGMP-degrading phosphodiesterase 5 ("PDE5"), Viagra affects the cGMP pathway. That pathway, in turn, promotes melanoma cell growth and migration.[7] Pfizer apparently failed to research or ignored signals in scientific literature since 2003 or earlier that Viagra-like drugs would be linked to melanoma. As a result, Pfizer has failed to warn the millions of patients and health providers who respectively use and prescribe this elective drug that it may cause cancer.

PDE5 inhibitors such as Viagra are scheduled to become available as generics in the United States in 2017, which typically results in even greater consumption due to significant reductions in cost to consumers.[8] In addition, PDE5 inhibitors are being increasingly used for

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[2] https://www.viagra.com/learning/what-is-ed (last visited May 1, 2016).
[3] https://www.viagra.com/learning/is-it-right-for-me (last visited May 1, 2016); *see also* Hilary Stout, *Viagra: The Thrill That Was*, N.Y. Times, June 5, 2011, *available at* http://query.nytimes.com/gst/fullpage.html?res=9B06E3DF173FF936A35755C0A9679D8B63 (last visited Apr. 29, 2016) (Pfizer estimates Viagra has been prescribed to more than 35 million men worldwide).
[4] https://www.viagra.com/learning/is-it-right-for-me.
[5] Jacque Wilson, *Viagra: The Little Blue Pill That Could*, CNN, Mar. 27, 2013, *available at* http://www.cnn.com/2013/03/27/health/viagra-anniversary-timeline/index.html (last visited Apr. 29, 2016).
[6] *See, e.g.*, Li, et al., *Sildenafil Use & Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 JAMA Intern. Med. 964 (2014); Arozarena et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating the cGMP-Specific Phosphodiesterase PDE5A*, 19 Cancer Cell 45 (2011).
[7] *See* Dhayade et al., *Sildenafil Potentiates a cGMP-Dependent Pathway to Promote Melanoma Growth*, 14 Cell Reports 1 (2016).
[8] *Id.* at 122 (listing companies likely to bring generic versions of Viagra to U.S. market on or after December 2017; Viagra recently lost exclusivity in the European markets in or around 2013). Pfizer has brought in over $5,274,000,000 in revenues from Viagra over the past three

additional indications, including treatment of prostate hyperplasia and pulmonary arterial hypertension "and there is tremendous growth of preclinical and clinical studies exploring new applications of PDE5 inhibitors, such as the management of cardiovascular diseases, diabetes, and even cancer."[9] As use of PDE5 inhibitors skyrocket, litigation of the warning issue is crucial.

I. PLAINTIFFS' CANCER INJURIES.

Melanoma Cancer: Plaintiffs in this MDL have all suffered melanoma cancer, and in certain cases death, arising out of their use of Viagra. Melanoma is a major public health problem.[10] It is the deadliest form of skin cancer, accounting for the majority of skin cancer deaths.[11] More than 9,000 Americans die of melanoma every year.[12] In recent years, its incidence has increased dramatically, new cases having doubled from 1982 to 2011.[13] The American Cancer Society estimates that in 2016, there will be about 76,380 new diagnoses of melanoma in the United States with over 10,000 deaths.[14]

Melanoma forms in melanocytes, the cells at the bottom of the epidermis that make the brown pigment called melanin which in turn gives skin its tan or brown color. Melanoma typically starts in moles (nevi) and grows larger and moves (invades) over time. Absent treatment, melanoma becomes metastatic, invading organs outside the skin. It is one of three types of skin cancer, the others being squamous cell carcinoma ("SCC") and basal cell

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years alone. Pfizer (PFE) Financial Rpt. (2015) at 25, *available at* http://www.pfizer.com/system/files/presentation/2015_Pfizer_Financial_Report.pdf (last visited May 1, 2016).

[9] Dhayade et al. at 9.

[10] Thompson et al., *Cutaneous Melanoma*, 365 Lancet 687-701 (2005).

[11] *See* Melanoma Research Foundation, http://www.melanoma.org/understand-melanoma (last visited Apr. 29, 2016).

[12] Centers for Disease Control & Prevention, http://www.cdc.gov/vitalsigns/melanoma/ (last visited May 1, 2016).

[13] *Id*.

[14] American Cancer Society, *Detailed Guide to Melanoma—Key Statistics* (hereinafter "ACS Melanoma Guide"), *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-key-statistics (last visited May 1, 2016).

carcinoma ("BCC"), neither of which are implicated in this case.[15]

Melanoma treatment is both significant and costly. Total melanoma treatment costs are about $3.3 billion annually in the United States.[16] The annual cost of treating newly diagnosed melanomas is estimated to increase from $457 million in 2011 to $1.6 billion in 2030.[17] A patient dying from melanoma loses an average of 20.4 years of potential life.[18]

Melanoma Diagnosis: Early detection and treatment of melanoma is essential to the survival of a cancer patient. Localized melanomas, accounting for approximately 84% of cases, have a 5-year relative survival rate of 98.4%, while distant melanomas—where the cancer has metastasized and spread to organs beyond the skin—have only a 17.9% survival rate.[19] The first sign of melanoma is not always obvious, oftentimes being a simple change in the size, shape, color, or feel of a mole.[20] Early diagnosis, while essential to survival, involves thorough medical examinations and invasive surgical procedures.[21]

Melanoma Staging: After diagnosis, a patient's melanoma is staged, which provides a standard way to describe how far the cancer has spread. The stage of melanoma is essential to treatment planning and patient prognosis.[22] The most common staging system is the American Joint Committee on Cancer ("AJCC") tumor, node, and metastasis ("TNM") system, which measures tumor size, extent, and penetration.[23] TNM system also measures the number of

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[15] *See* ACS Melanoma Guide—What is Melanoma?, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-what-is-melanoma (last visited May 1, 2016).
[16] Guy Jr. et al., *Vital Signs: Melanoma Incidence and Mortality Trends and Projections—United States, 1982-2030*, Div. of Cancer Prevention & Control, CDC, 64 Morbidity & Mortality Weekly Rpt. 591-96 (2015), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6421a6.htm?s_cid=mm6421a6_w (last visited May 1, 2016).
[17] *Id.*
[18] *Id.*
[19] Nat'l Cancer Institute, *SEER Stat Fact Sheets: Melanoma*, *available at* http://seer.cancer.gov/statfacts/html/melan.html (last visited May 1, 2016)
[20] Nat'l Institute of Health, U.S. Nat'l Library of Med., *MedlinePlus—Melanoma*, *available at* https://www.nlm.nih.gov/medlineplus/melanoma.html#summary (last visited Mar 1, 2016).
[21] ACS Melanoma Guide--Diagnosis, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-diagnosed (last visited May 1, 2016).
[22] ACS Melanoma Guide—Staging, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-staging (last visited May 1, 2016).
[23] *Id.* (listing melanoma T, N, and M values and descriptions); *see also* AJCC, *Cancer Staging Pamphlet*, *available at* https://cancerstaging.org/CSE/Registrar/Documents/needtoknow.pdf (last visited May 1, 2016).

lymph nodes with cancer and location of cancer-involved nodes and the extent to which cancer cells have spread outside the local area of the tumor.[24]

The TNM values are then combined to give the patient an overall stage, a process called "stage grouping." Patients with higher stage cancers generally have a more concerning prognosis.[25] Stages range from Stage 0 (melanoma *in situ*, i.e., in the epidermis without spreading to the lower dermis layer of the skin) to Stage IV (involving spread beyond the original area and nearby lymph nodes to other organs (lung, liver, brain) or distant nodes, areas of skin, or subcutaneous tissue).[26] Proposed Leadership anticipates that cases in this MDL will involve plaintiffs with all four stages of melanoma, including cases with deceased patients.

Melanoma Treatment: Melanoma treatment options include surgery, immunotherapy, targeted therapy, chemotherapy, and radiation therapy.[27] Wide excision surgery for early-stage melanomas involves slicing out the tumor along with an additional amount of skin beyond the tumor's edges, along with anesthesia, stitching, and scarring.[28] Amputation surgery may be conducted when a melanoma is on a finger or toe.[29] Lymph node dissection may take place, which may result in significant long-term side effects.[30]

Immunotherapy is sometimes the treatment of choice.[31] Targeted therapy likewise involves medicines, particularly drugs that attack gene changes which make melanoma cells different from normal cells.[32] These drugs include BRAF inhibitors (Zelboraf or Tafinlar), MEK inhibitors (Mekinist or Cotellic), and drugs that target C-KIT genes (Gleevac or

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[24] AJCC, *Cancer Staging Pamphlet*.
[25] ACS Melanoma Guide—Staging.
[26] *Id.*
[27] ACS Melanoma Guide—General Treatment Information, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-treating-general-info (last visited May 1, 2016).
[28] ACS Melanoma Guide—Surgery, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-treating-surgery (last visited May 1, 2016).
[29] *Id*.
[30] *Id*.
[31] ACS Melanoma Guide—Immunotherapy, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-treating-immunotherapy (last visited May 1, 2016).
[32] ACS Melanoma Guide—Targeted Therapy, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-treating-targeted-therapy (last visited May 1, 2016).

Tasigna).[33] Chemotherapy involves drugs that kill cancer cells, particularly melanoma cells (Dacarbazine, Temozolomide, Nab-paclitaxel, Paclitaxel, Carmustine, Cisplatin, Carboplatin, or Vinblastine), which are associated with a host of torrid side effects (nausea, vomiting, infection, bleeding, loss of appetite, and hair loss).[34] Finally, radiation therapy may be used whereby high-energy rays kill cancer cells.[35] Radiation is also associated with terrible side effects.[36]

Melanoma Follow-Up Care & Recurrence: Melanoma patients undergo significant follow-up, including life-long surveillance, necessary to check for signs of recurrence and treatment side effects.[37] A follow-up schedule includes regular skin and lymph node exams by both the patient and treating physician and occasionally imaging tests, such as x-rays and CT scans.[38] Physical exams are generally every 6 to 12 months for several years for patients who suffered early-stage melanomas and every 3 to 6 months for thicker melanomas that had spread beyond the skin.[39]

Despite successful treatment, a patient once diagnosed with melanoma is at a significantly higher risk than the general population of developing a new primary melanoma, as well as a recurrence of the original melanoma.[40] The overall lifetime risk of getting melanoma in the general population is about 2.4% (1 in 40) for whites, 0.1% (1 in 1,000) for blacks, and 0.5% (1 in 200) for Hispanics.[41] Recurrence 10 years or more after an initial treatment, however, has been found to occur in more than 1 in 20 patients and rates 25 years after treatment were even

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[33] *Id.*
[34] ACS Melanoma Guide—Chemotherapy, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-treating-chemotherapy (last visited May 1, 2016).
[35] ACS Melanoma Guide—Radiation Therapy, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-treating-radiation-therapy (last visited May 1, 2016).
[36] *Id.*
[37] ACS Melanoma Guide—Cancer After Follow-Up, *available at* http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-after-follow-up (last visited May 1, 2016).
[38] *Id.*
[39] *Id.*
[40] Floyd & Delores Jones Cancer Institute at Virginia Mason, *Melanoma FAQs*, *available at* https://www.virginiamason.org/melanomafrequentlyaskedquestions (last visited May 1, 2016).
[41] ACS Melanoma Guide—Key Statistics.

higher, at 11.3%.[42] When a recurrence of the original melanoma occurs, it is most commonly found in the regional lymph nodes (46%), followed by the original tumor site (30%) and distant sites (24%).[43]

The significantly high rate of a subsequent melanoma is especially concerning given that Viagra's labeling makes no mention of a melanoma risk in the first instance. The high recurrence rate combined with a Viagra user's already statistically significant increased risk of melanoma warrants additional warnings specifically directed at would-be Viagra users with any past diagnosis of melanoma.

II. SCIENTIFIC SUPPORT, SIGNALS & LACK OF WARNINGS.

Reliable science has suggested for years, and ultimately found as plausible, the mechanism by which PDE5 inhibitors such as Viagra impact melanoma development, increased invasion and growth. Without having reviewed any internal company document or clinical trial, and without any deposition or other discovery, peer reviewed scientific literature is currently available, supporting both a plausible biological mechanism of action and an epidemiological link between Viagra use and development of melanoma, to overcome any *Daubert*[44] challenge on general causation.[45]

Viagra was approved for sale in the United States in 1998. Its intended design is to inhibit the secretion of phosphodiesterase type 5 ("PDE5"), an enzyme responsible for the degradation of cyclic guanosine monophosphate ("cGMP"). When cGMP is not degraded by PDE5, smooth muscle in the corpus cavernosum relaxes, permitting an inflow of blood resulting in an erection. Despite their relatively quick therapeutic effects in a user's system, PDE5 inhibitors such as

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[42] American College of Surgeons, https://www.facs.org/media/press%20releases/jacs/melanoma0613 (last visited May 1, 2016); *see also* Pomerantz et al., *Risk of Subsequent Melanoma After Melanoma in situ & Invasive Melanoma: A Population-Based Study from 1973 to 2011*, 72 J. Am. Acad. Of Derm. 794, 796 (2015) (in cohort of 168,274 patients with diagnoses of melanoma between 1973 and 2011, 6.5% developed at least 1 subsequent melanoma; compared to general U.S. population, the risk of subsequent invasive melanoma in men originally suffering *in situ* melanoma was increased 8-fold and the risk of subsequent invasive melanoma in those originally suffering invasive melanoma was increased 13-fold).

[43] *Id.*

[44] *See Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

[45] *See* Fed. J. Ctr., *Reference Man. on Scientific Evid.*, pp. 597-606 (3d ed. 2011).

Viagra demonstrate a number of longer-lasting systemic side effects (cardiovascular flushing, central nervous system headaches, gastrointestinal dyspepsia, respiratory epistaxis, and ophthalmic visual disturbance).[46] That cGMP is a target of Viagra was well known when it was introduced to the market in 1998, indeed was the intended design of Viagra.[47]

Over the past several years, a number of studies have linked Viagra's mechanism of action to cell mutation that leads to melanomagenesis. For example, the role of cGMP in cancer has been a cause of concern in scientific literature dating back to 2003 or earlier.[48] In 2009, Packer *et al.* identified PDE5A as potentially being downregulated by oncogenic BRAF in melanoma cells.[49] In 2010, Murata *et al.* suggested that PDE5A might regulate the growth of melanoma cells.[50]

In January 2011, Arozarena *et al.* found that PDE5 inhibitors, including Viagra, promote melanoma cell invasion, particularly in *BRAF*-mutated cell lines.[51] Through inhibition of PDE5, Viagra mimics an effect of gene activation and therefore may function as a trigger for the creation of melanoma cells.[52] PDE5A impacts invasion of melanoma cells by regulating intracellular Ca2+ through cGMP.[53] Particularly concerning is the finding that "PDE5A drugs could promote melanoma metastasis" because "melanoma cells can rapidly evolve to become

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[46] Morales et al., *Clinical Safety of Oral Sildenafil Citrate (Viagra) in the Treatment of ED*, 10 International J. Impotence Res. 69 (1998).
[47] *See, e.g.*, Morales et al., *Clinical Safety of Oral Sildenafil Citrate (Viagra) in the Treatment of ED*, 10 International J. Impotence Res. 69 (1998); Walker et al., *Pharmacokinetics & Metabolism of Sildenafil in Mouse, Rat, Rabbit, Dog and Man*, 29 Xenobiotica 297 (1999).
[48] Dhayade et al., *Sildenafil Potentiates a cGMP-Dependent Pathway to Promote Melanoma Growth*, 14 Cell Reports 1, 2 (2016) ("cGMP has been implicated in the regulation of growth and survival in multiple cell types including tumor cells" (citing two studies from Feil et al. dating back to 2003 and 2005 respectively: Feil et al., *Cyclic GMP-Dependent Protein Kinases & the Cardiovascular System*, 93 Circ. Res. 907 (2003); Feil & Hoffman, *A Heretical View on the Role of NO and cGMP in Vascular Proliferative Diseases*, 11 Trends Mol. Med. 71 (2005))).
[49] Packer et al., *Identification of Direct Transcriptional Targets of (V600E) BRAF/MEK Signaling in Melanoma*, 22 Pigment Cell Melanoma Res. 785 (2009).
[50] Murata et al., *Expression & Role of PDE5 in Human Malignant Melanoma Cell Line*, 30 Anticancer Res. 355 (2010).
[51] Arozarena et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating the cGMP-Specific Phosphodiesterase PDE5A*, 19 Cancer Cell 45 (2011).
[52] *Id.*
[53] *Id.* at 53.

invasive, so any acceleration of this process is undesirable."[54]

In a January 2011 peer review of the Arozarena study, Mitra *et al.* emphasized the magnitude of the study noting:

> The clinical implication of this work which is likely to be most potentially concerning is whether patients taking PDE5A inhibitor drugs could be inadvertently increasing the invasive potential of melanotic lesions…. More concerning, however, may be that patients with very early-stage melanomas (that may not yet have been picked up clinically) may still express PDE5A at clinically meaningful levels (as suggested by the tissue microarray data), and these melanomas may be encouraged to switch to a more invasive state with PDE5A inhibition.[55]

In addition, studies published in 2012 found that PDE5 inhibitors promote melanin synthesis,[56] which may exacerbate melanoma development.[57]

In March 2016, Dhayade *et al.* determined that PDE5 inhibition with Viagra leads to increased tumor growth.[58] Specifically, melanoma cells express a cGMP pathway involving PDE5 and such pathway promotes MAPK signaling and melanoma cell growth and migration.[59] PDE5A (uninhibited) degrades cGMP, acting as a brake on the melanoma growth-promoting cGMP pathway.[60] Viagra, however, inhibits PDE5, thereby stopping it from degrading cGMP.[61] Without such degradation, Viagra leads to increased melanoma tumor growth.[62]

In an April 2016 peer review of the Dhayade study, Dr. Miles Houslay of the Institute of Pharmaceutical Science at King's College in London, highlighted the public health emergency at hand:

> Inhibitors of the cGMP-degrading phosphodiesterase (PDE) 5 have achieved blockbuster status in the treatment of penile erectile dysfunction (PED). Their

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[54] *Id.* at 55 (*citing* Balch & Cascinelli, *The New Melanoma Staging System*, 87 Tumori S64 (2001)).
[55] Mitra et al., *Melanoma & Viagra: An Unexpected Connection*, 1 Pigment Cell & Melanoma Res. 16, 17 (2011) (first published online Jan. 13, 2011).
[56] Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in B16 Melanoma Cells*, 113 J. Cellular Biochem. 2738 (2012).
[57] Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation Requires Melanin Pigment*, 3 Nature Communications 884 (2012).
[58] Dhayade et al., *Sildenafil Potentiates a cGMP-Dependent Pathway to Promote Melanoma Growth*, 14 Cell Reports 1 (2016).
[59] *Id.* at 3-4.
[60] *Id.* at 5-9.
[61] *Id.*
[62] *Id*.

> repurposing is currently being proposed to treat certain solid tumours and various other diseases. In cruel irony, however, it appears from recent clinical studies that PDE5 inhibitors may increase the risk of malignant melanoma by negating newly identified brakes on proliferation and metastasis provided by PDE5A.[63]

Verifying the Viagra-melanoma crisis found in biological studies, recent epidemiologic studies confirm that Viagra users have an increased risk of developing melanoma skin cancer.[64] In June 2014, an epidemiological study published in the *Journal of American Medical Association Internal Medicine* (the "JAMA Study"), found that Viagra use was associated with a statistically significant increased risk of developing melanoma.[65] Viagra users were 84% more likely to develop invasive melanoma compared to non-users.[66] The JAMA Study examined the direct relationship between Viagra use and melanoma development in men in the United States, studying a robust database population of U.S. male health professionals.[67] Health professionals are exceptional test subjects, considered to be highly motivated and committed to participating in a long-term project, to appreciate the accuracy of their reports, and to have relevant education concerning medical background.[68] Among the 25,484 participants, studied over a ten year period, the JAMA Study found that recent Viagra users at baseline had a significantly elevated risk of developing invasive melanoma, with a "hazard ratio" of 1.84. In other words, Viagra users exhibited an 84% increased risk of developing invasive melanoma.[69] Additional analyses demonstrated even stronger associations (1.92 HR for melanoma for "ever use" of Viagra; 2.19 HR when excluding outcomes occurring in the first two years; 2.18 HR when excluding users of

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[63] Houslay, *Melanoma, Viagra, & PDE5 Inhibitors: Proliferation & Metastasis*, 2 Trends in Cancer 163, 163 (2016).

[64] "Epidemiologic studies are the primary generally accepted methodology for demonstrating a causal relation between the chemical compound and a set of symptoms or a disease." Fed. J. Ctr., *Reference Man. on Scientific Evid.*, p. 553 n. 7, 11 (3d ed. 2011) (*citing In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 800 (N.D. Ohio 2004) *and referencing* Restatement (3d) of Torts: Liab. For Physical Harm § 26 (2010) (on tort law causation)). "When biological plausibility exists, it lends credence to an inference of causality." *Id.*, p. 604.

[65] Li, et al., *Sildenafil Use & Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 JAMA Intern. Med. 964 (2014).

[66] *Id.* at E3.

[67] The database consisted of the Health Professionals' Follow-up Study ("HPFS"), which began in 1986 when 51,529 U.S. male health professionals completed a baseline questionnaire on medical history and lifestyle practices. Biennially, participants receive a follow-up questionnaire with a response rate exceeding 90 percent.

[68] JAMA Study at E2.

[69] *Id.* at E3.

other ED treatments; 2.24 HR for "recent users" and 2.77 HR for "ever users" when excluding those with major chronic diseases at baseline).[70]

Despite the many, dire safety signals, Pfizer failed to study and warn Viagra consumers of the long foreseeable risk of cancer, which has sadly come to fruition in these cases.

III. CAUSES OF ACTION.

Plaintiffs generally allege product liability and negligence claims arising out of Defendant Pfizer, Inc.'s design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of Viagra. In particular, Plaintiffs have all used Viagra and thereafter suffered from melanoma skin cancer, which is linked to the use PDE5 inhibitors. Plaintiffs' cancer injuries and, in some cases deaths, were caused and exacerbated by Viagra use. Pfizer, for its part, should have known, researched, and investigated the potential association between melanoma and PDE5 inhibition, especially considering signals have been found in scientific literature for years. Plaintiffs and their treating and prescribing health care professionals were not warned (adequately or otherwise) that Viagra use is (or even might be) associated with the development or exacerbation of melanoma or cancer. Had they been warned or otherwise informed, Plaintiffs would have sought alternative treatments for ED or no treatment at all, particularly since ED is not life threatening and melanoma is the deadliest form of skin cancer.

Plaintiffs bring personal injury and product liability-related claims. Plaintiffs' causes of action are standard claims brought at the outset in pharmaceutical litigations before discovery focuses the conduct involved. The claims are based on state laws from their home forum states, the places of injury, the places of use, or any other locations consistent with applicable choice-of-law principles. The causes of action involved in this MDL include:

1) **Negligence and Strict Liability for Failure to Warn –** Pfizer's failure to use reasonable care in providing accurate information to the medical community and patients concerning Viagra's link to cancer;

2) **Negligence and Strict Liability for Defective Design** – Pfizer's failure to use

[70] *Id.*; *see also* Loeb et al., *Use of Phosphodiesterase Type 5 Inhibitors for ED & Risk of Malignant Melanoma*, 313 JAMA 2449 (2015) (also finding a statistically significant association between PDE5 inhibitor use and increased risk of malignant melanoma).

reasonable care in designing and testing Viagra such that it is not unreasonably dangerous to users;

3) **Wrongful Death & Survivorship –** Pfizer's failures proximately caused the death of Viagra users leaving behind surviving families and estates;

4) **Gross Negligence –** Pfizer's grossly negligent, reckless, and intentional abdication of responsibility concerning Viagra's life-threatening cancer side effects;

5) **Negligence Per Se –** Pfizer's violations of statutes and regulations concerning Viagra and its link to melanoma;

6) **Breach of Express and Implied Warranties –** Pfizer's breach of assurances to patients and health care providers concerning Viagra's safety, efficacy, and intended uses;

7) **Fraud, Deceit, Fraudulent Misrepresentation, Negligent Misrepresentation, and Concealment –** Pfizer's intentional, negligent, deceptive, and fraudulent representations to patients, health care providers, and the public concerning Viagra and risks of melanoma;

8) **Unjust Enrichment** – Pfizer's unjust acceptance of billions of dollars in revenues for a product that caused cancer; and

9) **Unfair and Deception Trade Practices** – Brought under California Business & Professions Code Section 17200 and applicable statutes and laws of Plaintiff's or Defendant's home forum, and relating to Pfizer's employment of unlawful, unfair or fraudulent business practices and deceptive, untrue, or misleading advertising.

Plaintiffs' causes of action also include allegations that Pfizer engaged in willful, wanton, reckless, and malicious conduct warranting punitive damages pursuant to applicable law.

None of Plaintiffs' claims involve preemption issues. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2478 (2013). Viagra and the other PDE5 inhibitors are branded drugs, not generics. *See Wyeth v. Levine*, 555 U.S. 555 (2009). There is no clear evidence that Pfizer ever sought a warning about Viagra causing melanoma from FDA and that FDA denied that request. *Cf. id.* at 571-572.

IV. ESTIMATED UNIVERSE OF CASES.

The undersigned, Proposed Lead Counsel for Plaintiffs, has surveyed all known attorneys with state and federal cases on behalf of individuals seeking redress for melanoma arising out of Viagra use. Plaintiffs estimate that the universe of cases involved is 750. Counsel has met and conferred with Defense Counsel and has agreed that Pfizer will submit a Schedule of all currently filed cases against it in this MDL and elsewhere.

V. MDL SCHEDULING CONSIDERATIONS.

The cases in this MDL will share a number of common and critical legal issues, including:

1) Discovery as to whether Defendant failed to adequately warn innocent consumers and health care professionals about the risks of cancer from Viagra use;

2) Discovery as to whether Defendant intentionally, deliberately, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed, or suppressed material and important information regarding the true and known risks of Viagra use from health care professionals, Plaintiffs, and patients in general;

3) Discovery as to whether Defendants' conduct in marketing, advertising, and promoting Viagra was negligent;

4) Discovery on all testing and clinical studies of Viagra (and its other PDE5 inhibitors);[71]

5) Discovery of Defendants' documents and witnesses relating to each and every claim alleged in Plaintiffs' Complaint;

6) Discovery as to Plaintiffs', their healthcare providers and other witnesses relating to their injuries and claims;

7) If damages are available to Plaintiffs, the method or methods by which such relief should be determined;

8) Whether Plaintiffs' scientific support, demonstrating a statistically significant increased risk of melanoma arising out of Viagra use and a plausible biological mechanism of action, passes muster under *Daubert* standards;

9) A bellwether trial selection process including case selection, case specific discovery, experts, and trials; and

10) Whether cases involving allegations against other manufacturers of PDE5 inhibitors (such as the manufacturers of Levitra and Cialis) should be consolidated in this MDL.

Proposed Lead Counsel for Plaintiffs and Counsel for Pfizer have begun initial discussions concerning a proposed discovery plan. Counsel are in general agreement that the initial phase of this litigation should focus on issues related to general causation. Counsel plan

[71] For example, Pfizer states that it is currently engaged in "major research efforts" concerning new medical solutions, including a key product in "Phase 2" that it describes as "PDE5 inhibitor: Diabetic Nephropathy." *See* http://www.pfizer.com/research/science_and_technology/product_pipeline (last visited Apr. 29, 2016). Pfizer's research related to this product and melanoma, or lack thereof, is highly relevant to critical legal issues in this MDL.

to meet and confer further in person, with representatives from Plaintiffs' proposed discovery committee, prior to the Scheduling Conference scheduled for June 15, 2016. Plaintiffs anticipate that the discovery plan will include proposed Case Management Orders dealing with scheduling discovery, *Daubert* hearings, and the bellwether trial process.

Respectfully submitted,

Dated: May 9, 2016

CORY WATSON, P.C.

/s/ Ernest Cory

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, a true and correct copy of the foregoing was filed and served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Ernest Cory
Ernest Cory